PSJ15 Exh 106

Order Monitoring System (OMS): A Manufacturer's Perspective

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Mission of the Purdue OMS Program

To ensure compliance with DEA regulations requiring manufacturers and distributors to monitor and report suspicious orders of controlled substances, by implementing a detailed process for:

- **Ongoing assessment of selected accounts, including Purdue's authorized distributors and their retail customers**
- **Support for authorized distributors in implementing their OMS programs and efforts to "know their customers"**
- **Reporting of suspicious ordering to DEA, other law enforcement, or state licensing boards, as appropriate**

History of the Purdue OMS Program

- **Followed DEA correspondence to all registrants detailing obligations of manufacturers and distributors of controlled substances to:**
  - **Conduct independent analysis and exercise due diligence to confirm legitimacy of orders and to scrutinize suspicious circumstances**
    - Valid DEA registration not sufficient
    - Know your customers and your customers' customers
  - **Inform DEA of suspicious orders when discovered**
- **Expanded program launched in 2008**
- **SOP finalized in March 2009**

OMS Program Team Members

OMS COMMITTEE CHAIRPERSON

VP & Associate General Counsel, Law Department

MEMBERS

VP, Corporate Security
Executive Director, DEA Compliance
Executive Director, National Accounts
Director, OMS Program Coordinator
Director/Investigations, Corporate Security

CONTRIBUTORS

VP, Health Policy
Attorney, Prescriber Program analysis
Professional Rep, Sales Force
Director, Sales Systems

OMS Information Sources

- **Fee For Service (FFS) Data**
  - Order data for pharmacies + other dispensing outlets
  - Provided by authorized distributors under FFS Agreements
  - Loaded on monthly basis into OMS Database
  - Cover 97% of Purdue's product distribution
- **IMS outlet/prescriber data & Sales Ops outlier analyses**
- **Sales Force reports of concern (ROC)**
- **Prescriber Program information**
- **Government agencies/law enforcement**
  - DEA, local law enforcement, state licensing boards, legislative contacts
- **Media reports**

Prescriber versus Dispenser

- **Prescriber program: Focus is on prescriber and Rx history /patterns**
- **OMS: Focus is on dispenser/pharmacist and ordering history/patterns**
- **Sharing of signal detection information between OMS and Prescriber programs**
  - **Enables us to consider prescriber and pharmacy issues within particular geographic area**
  - **Results in more robust information shared with internal (e.g., Risk Management) and external (e.g., authorized distributors) partners**

OMS Process

➢ Identification of Potential Problematic Outlets ('09-'10)

- **FFS Data Outliers – Outlets with orders outside normal range based on algorithm:**
  - Total volume of Purdue product orders
  - Percentage of OxyContin / non-OxyContin orders to total orders of Purdue products
  - Percentage of orders of higher dosages of OxyContin
  - Number of distributors from which outlet purchases
  - Number of orders of same product per day
  - Significant increases/changes comparing current 1, 3, 6 and 12 months to prior period

Based on algorithm, **500-600 outlets met criteria**

OMS Process

(continued)

➢ Identification of Problematic Outlets (continued)

- **IMS Data Outliers**
  - Outliers among retail outlets identified by Sales Ops' quarterly analysis of IMS Data
- **Outlets identified by other signals**
  - Typically identified by sales force or authorized distributors
  - Suspicious signals include:
    - Observed anomalies of pharmacy location, appearance/operation or clientele
    - Statements by pharmacy personnel indicating deficiencies in Rx verification or other abuse/diversion mitigation procedures
    - Authorized distributor comparative data on other opioid dispensing by pharmacy or Rx detail on pharmacy's prescribers
    - Media reports of law enforcement or licensing board action

OMS Process

(continued)

- **Outlier Pharmacies Selected for Review:**
  - Top FFS Data Outliers (as ranked by Sales Ops)
  - Accounts identified by authorized distributors
- **Input from National Accounts**
  - Any prior knowledge of pharmacy, including factors that explain or heighten concern about outlier data
  - Assessment of need for further follow up
- **Input from Sales Force**
  - Review of prior ROCs
  - Standard OMS follow with Rep / DM / RM
  - Specific additional assistance occasionally requested

OMS Process

(continued)

- **Review of Related Internal Data & Information**
  - Savings Card Pharmacy Redemption data
  - Analysis of identified prescribers (IMS data)
- **Public Records Search**
  - Corporate security review of entity status and ownership, including related entities
  - DEA registration / state licensing status and disciplinary actions
  - Civil or criminal actions

OMS Process

(continued)

- **DEA Compliance: Collaboration with Authorized Distributors**
  - **Initial meetings to share information about respective order monitoring programs and procedures**
  - **Ongoing information exchange and review of ordering data and other information pertaining to specific outlets**
  - **Communication and collaboration on follow up with respect to individual outlets, which may include:**
    - Outlet surveillance and/or site visit and interview of owner, Pharmacist-In-Charge and/or pharmacy staff
    - Reduction or cut-off of supply to outlet
    - Reporting to licensing board, DEA, other law enforcement

Summary of OMS Meetings

- **Order monitoring meetings held with authorized distributors plus ongoing contacts:**
  - **Between Sept 2008 and March 2012, Purdue met in person with 10 separate wholesalers to discuss OMS programs and procedures, and opportunities for better collaboration**
  - **Throughout that time, Purdue engaged in regular ongoing contact via conference calls and joint site visits to discuss particular accounts of concern and appropriate follow up**

OMS Process

(continued)

➢ OMS Report and Committee Decision

- **Written report for OMS Committee review**
  - Generated by Program Coordinator for each "outlier outlet"
  - Captures information obtained during OMS review process
- **OMS Committee decision on each outlet reviewed**
  - Pending: No decision pending completion of requested follow up
  - Complete-closed: No suspicious ordering concern
  - Complete-referred: Evidence of suspicious ordering and/or circumstances sufficient to refer to DEA, other law enforcement and/or state licensing board
  - Continue to monitor: Suspicious circumstances warrant close monitoring, but not yet sufficient to refer
- **OMS Committee may recommend adjustments in shipments to distributor due to OMS concerns**

OMS Process: Post Reformulation

- **Updated Algorithm Based on Reformulation ('10 – '11)**
  - **FFS Data Outliers – Outlets with decline in orders post OxyContin reformulation that met the following:**
    - Orders that met original algorithm
    - Significant declines/changes comparing current 3, 6 and 12 months of pre- versus post-reformulation data
    - Threshold 75% decline post reformulation
    - Percentage of OxyContin decline post reformulation vs contemporaneous increase in other opioids
    - Evaluate whether geographically located near prescribers of concern
    - Adjust threshold ($) to focus on significant accounts for review

Based on new algorithm, **100 to 200 outlets met criteria**

Meetings with DEA

- **April 2009**
  - Overview of OMS program
  - Described collaboration with authorized distributors
- **April 2011**
  - Overview of updated Purdue OMS program following reformulation
  - DEA Registrant book shared
  - Focus on prescriber data post-reformulation
- **October 2011**
  - Focus on retail dispensing post-reformulation
  - At request of DEA, provided calculation of all outlets with at least 50% decline and $350,000 in annual sales
  - Total of 290 outlets identified (29 previously identified)

Summary of OMS Program Activity

(continued)

➢ Outlets Reviewed and/or Referred ('08 – '11)

- **Total: 365**
- **Breakdown by state:**
  - FL : 94
  - CA: 55
  - NY: 39
  - MI: 38
  - PA: 18
  - TN: 14
  - OH: 13
  - 27 States: 94 (3 to 4 each)
- **Breakdown by OMS Committee Action:**
  - Complete-Referred: 290
  - Complete-Closed: 75
  - Continue to Monitor: 8

Summary OMS Program Activity

(continued)

➢ Outlets pending review/investigation

- **Total: 8**
- **Breakdown by state:**
  - GA = 3
  - NY/NJ/CA/TN/IN = 5 (1 each)

➢ Outlets subject to OMS Team Surveillance or Site Visits

- **13 pharmacy site visits including interviews with owners or pharmacists in charge**
  - 6 of the visits conducted together with authorized distributors
  - Breakdown by location: 8 in Florida, 2 in California and Nevada, 1 in NY
- **10 additional pharmacies subject to surveillance**
  - 5 in California , 2 each in Ohio and Florida, 1 in Nevada
- **30 + site visits with wholesalers**

OMS Program Challenges

- **Data Gaps**
  - **No data connecting outlets with individual prescribers**
  - **No data from distributors with whom we have no FFS agreement**
  - **FFS data excludes outlet-level order detail for:**
    - Secondary distributors
    - Dispensing outlets that opt out of data reporting
  - **IMS data excludes prescribers/outlets who opt out of reporting**
  - **Dispensing healthcare providers**
- **Not in doctors office, or at pharmacy, when prescriptions being written and filled**
- **Pressure Created by Geographic Hotspots (e.g., Florida, California, Tennessee, Georgia and Alabama)**

Recommendations: Lessons Learned

- Quantities matter: excessive orders must be evaluated
- Meaningful scrutiny of dispensing: registration not sufficient
- Site visit due diligence: expected as part of follow up
- Cannot rely on third party: must do own due diligence
- Trend analysis is a key: compare similar products, size and location of outlets
- Threshold exceptions: must be individually reviewed and decisions properly documented
- Referrals to DEA: consider for all OMS actions regarding outlets

Benefits of Collaboration: What can be gained?

- Enhance collaborations efforts between wholesalers and manufacturers
- Greater information sharing: maximize resources (DEA, Wholesaler and Manufacturer)
- Achieve efficiencies with accounts identified for follow up
- Identify additional tools to address DEA's concerns (better data analysis, potential modeling)
- Mindful of anti-trust concerns

Thank You

Any Questions